



Second AIMBE Workshop on Validation and Qualification of New *In Vitro* Tools and Models for the Pre-Clinical Drug Discovery Process

September 17

Day 1

8:00-8:45 AM

Continental Breakfast and Check-In

8:45-9:00 AM

Welcome and Goals of the Workshop

James Hickman, PhD, University of Central Florida, AIMBE BOD member

9:00-9:25 AM

Welcome from the AIMBE President

Raphael Lee, MD, ScD, University of Chicago Medicine

Session 1:

Current Perspectives on Validation and Qualification

Moderator: Christine A. Kelley, PhD, NIBIB/NIH

9:25-10:10 AM

Validation of New Technology by NICEATM/ICCVAM

William S. Stokes, DVM., DACLAM ;Executive Director ICCVAM

10:10-10:35 AM

Break

10:35-11:20 AM

Validation of New Technology for Use in Drug Discovery in Europe

Sonja Beken, PhD, Belgian Federal Agency for Medicines and Health and the European Medicines Agency

11:20-12:00 AM

Validation of New Technology from an Industry Perspective

Jack Reynolds, PhD, AnaBios Corporation

12:00-1:30

Lunch

Session 2:

In Vitro Technologies for Draft Validation Guidelines

Moderator: James Hickman, PhD, University of Central Florida, AIMBE

1:30-2:15 PM

NIH Technologies for Pre-clinical Regulatory Science.

Dan Tagle, PhD, NCATS/NIH

2:15-3:00 PM

Validation of New Technology from a Developer Viewpoint

William Warren, PhD, Sanofi Pasteur

3:00-3:30 PM

Break

3:30-4:15 PM

Validaton of New Technology from a NIST Point of View

Anne Plant, PhD, NIST

4:15-5:00 PM

High Content Screening:

Michael Jackson, PhD, Sanford Burnham Research Institute



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5:00-5:30 PM	Group Discussion and plans for day 2
5:30-7:30 PM	Reception-Lister Hill Lobby
September 18	Day 2
8:00-9:00 AM	Continental Breakfast
Session 3: 9:00-9:20 AM	Development of Draft Validation Guidelines <i>Moderator: James Hickman, PhD, University of Central Florida, AIMBE BOD member</i>
9:20-10:00 AM	Experience using PBPK Models in Clinical Pharmacology Reviews <i>Ping Zhao, PhD, Clinical Pharmacology CDER/FDA</i>
10:00-10:40 AM	Human Body-on-a-Chip Systems <i>Michael Shuler, PhD, Cornell University</i>
10:40-11:00 AM	<i>Break</i>
11:00-12:00 AM	Discussion of topics by AIMBE breakout session leaders. 20 minutes each.
12:00-1:15	Lunch
1:15-3:00 PM	Breakout group discussions on validation guidelines
3:00-3:30 PM	<i>Break</i>
Session 4:	Results from Breakout Groups <i>Moderator: TBA</i>
3:30-3:45 PM	Breakout Group 1 Report—AIMBE FELLOW #1
3:45-4:00 PM	Breakout Group 2 Report—AIMBE FELLOW #2
4:00-4:15 PM	Breakout Group 3 Report—AIMBE FELLOW #3
4:15-5:00 PM	Final Group discussion and future directions
5:00 PM	Adjourn